IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **Wave 1 cases listed in Exhibit A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF JOSEPH CARBONE, M.D.

Plaintiffs respectfully request that the Court preclude defense expert Joseph Carbone M.D., a urogynecologist, from giving opinions on (1) the safety and efficacy of Defendants' products based on his own clinical practice; (2) the design of Defendants' transvaginal mesh products at issue, including the safety and efficacy of those devices; and (3) the adequacy of Defendants' product warnings and instructions for use ("IFU").

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158.

ARGUMENT

This Court should prohibit Dr. Carbone from giving the opinions referenced above because he is not qualified to opine on those issues and has not done the necessary research to produce opinions that can reliably be applied to this case. Dr. Carbone produced two reports

addressing the following products: a 23-page report covering TVT, TVT-O, TVT-Secur (the "TVT Report") and a report on Prolift (collectively, the "subject products"). The two reports contain the same general opinions/statements:

- Defendants' products at issue are not defective; they were reasonably safe for their intended uses. The benefits of Defendants' product outweigh the risk of using the product, and they are safer and better than the non-mesh alternatives. (*See* TVT Report, attached as Exhibit B, at 23; Prolift Report, attached as Exhibit C, at 24-25).
- The IFU and/or the warnings concerning Defendants' subject product are adequate and allow for the safe use of the device. (*See* TVT Report, Ex. B, at 20; Prolift Report, Ex. C, at 26).
- Regarding the safety and efficacy of Prolift: "I practiced and have successfully performed the technique without major complication." (*See* Prolift Report, Ex. C, 2). Notably, Dr. Carbone made no similar statement about the TVT products.

The first bullet point relates to Dr. Carbone's attempt to bolster his design defect opinion based on his own experience as to the safety and efficacy of Defendants' products. As discussed in greater detail below, this is Dr. Carbone's attempt to backdoor into evidence an improper and unsupported opinion on his personal complication and/or success rate.

For the reasons described below, Dr. Carbone should not be permitted to give those opinions under the standards set by Rule 702 and *Daubert*.

I. Dr. Carbone's statements about his personal perceived experience related to the safety and efficacy of the subject products should be excluded because he admitted he did not perform a systematic review and that he does not track his patients; so his stated rates are inconsistent and unreliable, they are not in line with rates reported by surgeons in peer-reviewed medical literature and, finally, has not provided any documentation to support his imprecise generalized rates.

Dr. Carbone should be precluded from testifying about his perceived safety and efficacy rates with the subject product from his own practice, as that information is entirely unsupported by any meaningful statistical information or analysis. This exclusion should include any imprecise general personal complication or success rates, and any imprecise patient follow-up rates. For instance, Dr. Carbone states in his Prolift report that he had no major complications in his use of Prolift. But at his deposition, Dr. Carbone admitted he had not done a study or survey to ascertain his complication rates, that he did not know how many Prolift complications he experienced in his practice, and that he "lumped" together his Prolapse product failures. (Carbone TVT Deposition Day One, March 16, 2016, portions attached as Exhibit D, at 69:21-70:12). Dr. Carbone further testified as follows:

> Q. Have you ever endeavored to do a survey or study of your exact complication rate?
>
> A. THE WITNESS: Not my exact complication rate.
>
> Q. Okay. How about have you ever done a survey or study to discover your exact failure rate?
>
> A. THE WITNESS: Not my exact failure rate.
>
> Q. So you can't tell us one way or the other your precise success rate with the use of mesh, correct?
>
> A. Not -- my precise.
>
> Q. Have you ever attempted to create a registry with your mesh patients? A registry that tracks your patients, say, five years down the road?
>
> A. No.

(*Id.* at 70:13-71:10). Unlike several other Ethicon expert witnesses, Dr. Carbone testified that his rates **are not** in line with what other surgeons have studied, analyzed and reported in peer-reviewed medical literature.

> A. I would say my complication rate was a little lower than the reported complication rate in the medical literature, the randomize control trial, the analysis.
>
> Q. And would be this be for the TVT products?
>
> A. For the TVT products and also for some of the Prolene -- sorry, the Prolift product and Prosima.
>
> Q. Okay.
>
> A. I should say prolapse products. I put them all together.

(Carbone TVT Deposition Day 2, March 17, 2016, portions attached as Exhibit E, at 110:10-20).

When pressed, Dr. Carbone admitted he did not perform any systemic review of his mesh practice and simply assumed what his rate was based on an unreported, unsupported and undisclosed summary by his office assistant of some of his patients and excluding any patients which were subsequently treated by other physicians.

> I mean, I looked at like a survey of a couple of years back and extrapolated based on the number of procedures that I've done. You're absolutely right, I didn't do a systematic review. I mean, a systematic review rises -- I mean, you know, I didn't do a systematic review, no. I don't believe I said I did a systematic review.

(Carbone TVT Day 2, Ex. E, at 153:8-18).

Defendants previously had their witnesses testify to specific practice complication rates, before apparently realizing that such unsupported rates were inappropriate, unsupported and inadmissible. But now, instead of having the witness or a statistician to analyze the relevant patient data, witnesses such as Dr. Carbone now seek to back-door essentially the same opinion by stating that he believes he experiences lower than reported complication rates in his practice, without identifying a specific rate. This imprecise opinion should not be permitted, as Dr.

Carbone lacks any data or analysis to support his conclusions—especially when Dr. Carbone did not state his rates in his alleged reports or produce a single document to support the opinion.

As such, plaintiffs have no reasonable way of testing the veracity of Dr. Carbone's "rates," which exist only in his mind. Because there is no foundation for this testimony, Dr. Carbone should be prohibited from providing this testimony. An exchange about Dr. Carbone's alleged imprecise patient follow-up rate, shows how unreliable imprecise generalized testimony on these subjects can be.

> Q. You said earlier, when Mr. Rosenblatt was questioning you, that you believe your patient follow-up is pretty high?
>
> A. I believe so.
>
> Q. Is that an opinion you intend to offer at trial?
>
> A. That I believe it's pretty high?
>
> Q. Yes.
>
> A. Yeah. I believe it's pretty high.
>
> Q. You believe you can state that to a reasonable degree of medical certainty, that your follow-up rate is pretty high?
>
> A. You know, greater than 50 percent follow-up with me.
>
> Q. My question was: Do you believe you can state to a reasonable degree of medical certainty that your patient follow-up is pretty high?
>
> A. I believe I can.
>
> Q. So what is your patient follow-up rate, and how did you determine that?
>
> A. I think it's greater than half, and I determined it based on –
>
> Q. Can you be any more specific than greater than half? Do you have a percentage?
>
> A. No, I don't.

Q. Do you know what follow-up rates are for physicians in your area?

A. For physicians in my area, no.

(Carbone TVT Day 2, Ex. E, at 154:13-155:16).

Moreover, Rule 26 requires an expert report to contain "a complete statement of all opinions the witness will express and the basis and reasons for them[.]" Fed. R. Civ. P. 26(a)(2)(B)(i). Here Dr. Carbone made no effort to include any mention of his alleged personal TVT rates and was limited in his Prolift report to a single statement that he had no major complications with his Prolift technique. Thus, additional grounds exist for excluding these unreliable and unsupported opinions about low complication rates and high follow-up rates.

Finally, while Dr. Carbone stated that he "probably reviewed" articles about why physicians struggle to report accurately their complication rates, he could not recall anything about what he had "probably reviewed" on this issue.

Q. Medical literature that concludes physicians, like yourself, aren't familiar, don't know the success rates with their patients when they use transvaginal mesh.

A. I probably reviewed it.

Q. Okay. And why is it that physicians don't know their success rates when it comes to their use of transvaginal mesh?

A. THE DEPONENT: I don't know.

Q. You don't know. Could it be because they don't track their patients?

A. I mean, you can speculate that.

Q. You can speculate, but you don't know, as you sit here today?

A. No.

(Carbone TVT Day 2, Ex. E, at 141:3-20).

II. Dr. Carbone's does not know what an expert in of warnings related to the TVT mesh would be, does not know the industry standards for what warnings must be in IFUs, does not know the regulatory standards for what warnings must be in an IFU, and does not know what standards Ethicon used for what warnings were included in the product IFUs. Moreover, he does not rely on IFUs in his normal practice; thus, his opinions on these issues should be excluded.

This Court has recognized the importance of an expert's admission that he is not an expert in the area of warnings. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). Dr. Carbone testified during the first day of his deposition:

> Q. Are you an expert on warnings?
>
> A. I'm sorry?
>
> Q. I'll withdraw that last question. Are you an expert on warnings?
>
> A. Warnings?
>
> Q. Warnings related to TVT mesh.
>
> A. Warnings related to TVT mesh. I'm trying to consider what an expert in warnings would be. Again, I don't know what an expert in warnings would be.
>
> Q. Have you ever drafted an IFU?
>
> A. No.
>
> Q. Do you rely in your normal course of practice as a physician on IFUs?
>
> A. Do I rely?
>
> Q. (Nodding head up and down.)
>
> A. No.
>
> ***
>
> Q. … Are you aware the industry standards that govern what warnings must be in an IFU?
>
> A. The industry standards? No, I don't know that --

Q. Do you agree that all material risks related to the TVT mesh must be included in the IFU?

THE WITNESS: I guess define "material risk."

Q. It's in your report. How do you use it? I'm using your term.

A. I understand. I just wanted to know on how you were using it in your question.

(Off record discussion.)

Q. I wish I could let you take all day, Doctor, but we're on a tight time frame.

A. I apologize. I just don't see where I write on this TVT IFU section the term "material risk." If you would like to point out to me specifically where I'm using it, I'll be happy to cut to the chase for you.

Q. Yeah. Why don't you go to page 4? First sentence, page 4.

A. Oh. That's under the section of informed consent. Okay. Let me look at that.

Q. So I'm using your term "material risk." Okay?

A. Okay. But that --

Q. See that? You see the words?

A. But that -- yeah, I see the word right there.

Q. All right. Let me ask my question.

A. Go ahead.

Q. Is it your opinion that the TVT IFU should include all material risks associated with the device?

THE WITNESS: And I know we're under a time restraint, so I'll respect that by answering I can't answer your question, because I use the term "material risk" in my discussion on informed consent between surgeon and patients, not on the discussion in an IFU. I use the term differently. So if you want to define what you mean by "material risk in an IFU," I'll be happy to try to answer your question.

> Q. Same what you mean in your report when you're discussing it in that section. That's what I mean.
>
> A. Oh, I understand.
>
> Q. So same question, yes or no. Does the IFU for the TVT need to include all material risks associated with the device? Yes or no or I can't answer the question?
>
> THE WITNESS: I can't answer the question for IFUs.
>
> ***
>
> Q. Do you know what standards Ethicon applied in terms of what needed -- what warnings needed to be included in the IFU about Prolift?
>
> A. The standards that Ethicon applied?
>
> Q. Yes.
>
> A. I'm not familiar with what the standards Ethicon applied, no.
>
> ***
>
> Q. Have you made any effort before today to find out what FDA guidelines require a medical device company to put in an IFU?
>
> A. No.

(Carbone TVT Day 1, Ex. D, at 123:1-17, 124:1-126:12; Carbone Prolift Deposition, March 16-17, 2016, portions attached as Exhibit F, at 42:5-11, 49:24-50:2).

When pressed on March 17, Dr. Carbone stood by this testimony and testified he was not changing any of his testimony from the prior day's deposition. (Carbone TVT Day 2, Ex. E, at 138:13-15).

Importantly, Dr. Carbone was a paid consultant under contract with Ethicon for a decade, claiming to have been paid almost a half of million dollars for his consulting fees. But at no time did Ethicon ever ask him to assist in any way in drafting any IFUs or warnings statements, much

less IFUs or warnings related to mesh, and not a single medical device company ever asked him to be an expert on IFUs or product design in his career.

> Q. And it's fair to say from -- starting in the year 2003 through the year 2012, for each of those years, you received payments from Ethicon for your role as a consultant physician, correct?
>
> A. Correct.
>
> Q. It's fair to say, between the years 2003 to 2012, every single one of those years, you performed work for Ethicon as a consultant physician, correct?
>
> A. Correct.
>
> Q. It's fair to say before you agreed to be a litigation consultant for Ethicon, you had a ten-year relationship with Ethicon in your role as a consultant physician, correct?
>
> A. 2003 till when?
>
> Q. To the end of 2012.
>
> A. Yes.
>
> ***
>
> Q. Okay. And am I correct in saying, between the years 2003 to 2012, Ethicon paid you, according to Exhibit 5, $452,398?
>
> THE WITNESS: As a consultant, yes.
>
> ***
>
> Q. Have you ever assisted a medical device company in drafting an IFU?
>
> A. No.

(Carbone TVT Day 1, Ex. D, at 14:6-22, 92:4-9; TVT Day 2, Ex. E, at 65:1-3).

For all of these reasons, Dr. Carbone does not have the necessary expertise under Daubert and Rule 702 to give opinions about the sufficiency of warnings in the IFU for the subject products. The Court, therefore, should exclude those opinions.

III. Dr. Carbone should be precluded from giving design opinions because the lacks the necessary knowledge or expertise on the topic.

There are several reasons why Dr. Carbone should be precluded from giving opinions as to the design and safety of the subject products, including:

1) Even though he was a paid consultant for the Ethicon for a decade, Ethicon never asked or considered Dr. Carbone to be a design expert;

2) Dr. Carbone reviewed only 10 to 15 internal Ethicon documents total;

3) Dr. Carbone only used Ethicon mesh products in women such that he has no basis for comparing any design aspects of Ethicon products to any other devices;

4) Dr. Carbone could not answer whether Ethicon mesh can cause pain or painful sex (two of the primary issues in this litigation), even though he bases his supposed design and safety expertise almost exclusively on his high usage of the Ethicon mesh; and,

5) He lacks basic knowledge of the facts of this case, including some addressed in his expert report.

First, Ethicon never considered Dr. Carbone a design expert in his time since 2003 acting as a paid consultant for Ethicon, until waves of cases were set for trial. He did perform marketing events for Ethicon, however.

> Q. Is it fair to say that, in your consulting work between the years 2003 and 2012 for Ethicon, some of the events you conducted for Ethicon were marketing events?
>
> A. Yes.
>
> ***
>
> Q. Ethicon's never asked you to help them design a mesh product for the treatment of stress urinary incontinence?
>
> A. No.

****

Q. Now I've got to ask you again. Yes or no. To the best of your recollection, has a medical device company other than Ethicon ever asked you to act as an expert in litigation?

A. Is it the same question?

Q. Yes or no?

A. Was my answer inadequate?

Q. Yes or no?

A. Not that I recall.

(Carbone TVT Day 1, Ex. D, at 15:18-22; Carbone TVT Day 2, Ex. E, at 65:13-16; Carbone TVT Day 1, Ex. D, at 91:8-18).

Dr. Carbone should also be precluded from opining about the design of the subject products because he has not reviewed Defendants' internal documents about the design process. This issue was central to the exclusion of design opinions by a urogynecologist for the plaintiffs in the Boston Scientific litigation. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015). Boston Scientific Corp. ("BSC") moved to exclude Dr. Shull because he "reached opinions on the improper design of the Uphold without having first considered BSC's design protocols." The plaintiffs countered that Dr. Shull had relied on other BSC internal documents, as well as the scientific literature. *Id.*

This Court agreed with BSC and excluded Dr. Shull from giving any design opinions. This Court reasoned that "regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from Dr. Shull's methodology. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

Similarly, Dr. Carbone has read very few internal documents in reaching his opinions for this case. He confirmed repeatedly that he did not review Defendants' internal operating procedures or any other internal design documents in formulating his opinions. Because he did not review the relevant design documents, Dr. Carbone lacks the required knowledge to give a reliable opinion about the design of Defendants' transvaginal mesh products.

But Dr. Carbone went a step further and additionally did not review key TVT design documents in this litigation used at multiple trials, including the contract between the inventor of TVT and Ethicon detailing milestone payments to the inventor and documents related to getting to market TVT-O. And unlike Dr. Shull and other experts, Dr. Carbone was a consultant for Ethicon for a decade, giving him special access to Ethicon internal documents. Neither during this litigation or during that decade period did Dr. Carbone review more than 10 to 15 internal Ethicon documents.

Q. … Did you review any internal Ethicon documents?

A. Some of it is.

Q. Some?

A. Yeah.

Q. Okay. How many?

A. Not -- a minority.

Q. Very small amount of internal Ethicon articles for you to review?

A. A minority. How do you define "very small," right?

Q. Did you review more than 100 internal documents?

A. No.

Q. Did you review more than 50?

A. I don't think so.

Q. Okay. If you want -- I think I've looked at your reliance list. There's about 10 –

A. Yeah.

Q. -- 10 --

A. Yeah.

Q. So 10 or 15 internal documents, okay.

A. Yeah. Not many at all.

Q. Just so the record -- you reviewed a total of 10 to 15 internal Ethicon documents, correct?

A. See the reliance list. Yeah.

(Carbone TVT Day 1, Ex. D, at 42:18 to 43:18).

Q. How about, did you review the design specifications for any of the products that we're discussing here today?

A. I don't remember specifically.

Q. As you sit here today, you don't have any recollection reviewing the design specifications for the TVT line of products for the Prolift, correct?

A. I do not have any specific recollection of those things.

(*Id.* at 44:8-16).

Q. Have you reviewed any internal documents related to how the TVT Obturator was developed to market?

A. Did you ask internal documents?

Q. (Nodding head up and down.)

A. I reviewed a few, but I don't recall specifically something about that, no.

Q. None specifically that spoke to the time it took to get TVT-O to market?

A. No.

Q. Have you reviewed the contract between Ethicon and Dr. Ulf Ulmsten?

A. No.

(*Id.* at 113:3-15).

Q. Okay. Are you familiar with the concept of milestone payments?

A. I'm sorry?

Q. Are you familiar with the concept milestone payments in the context of study – studies and trials and analyzing data?

A. No, I'm not familiar with that.

Q. You've never heard the term "milestone payment"?

A. I have not.

(*Id.* at 36:16-25).

Dr. Carbone also seemed to not know the concepts and literature discussed in his reports.

Q. Do you know who Christian Falconer is?

A. No.[1]

(Carbone TVT Day 2, Ex. E, at 23:16-17).

Finally, because Dr. Carbone only used Ethicon transvaginal mesh products, he lacks any expertise or experience in the relative safety profile of Ethicon mesh products, whether Ethicon mesh products are state of art, or how the design features of Ethicon mesh products compare to other medical devices. This is important when a witness almost entirely bases his opinions on his high usage of the products at issue but cannot answer whether Ethicon mesh can cause pain or dyspareunia, two of the primary issues in this litigation.

[1] The reports produced for Dr. Carbone in this litigation discuss Christian Falconer in both his TVT report and in his Prolift report. In fact, Falconer is the sole support for Dr. Carbone's opinion that TVT mesh elicits no tissue reaction at two years and nearly half a page of the 23 page report covering TVT, TVT-O and TVT Secur is devoted to discussing Falconer. (*See* TVT Report, Ex. B, at 16; Prolift Report, Ex. C, at 25). Thus, at the very least any opinions of Dr. Carbone related to this issue should be stricken.

> Q. Have you ever used any mesh products transvaginally since the year 2000 that are not made by Ethicon?
>
> A. No.
>
> ***
>
> Q. Can TVT mesh cause chronic pain?
>
> THE WITNESS: I mean, I guess -- I kind of feel like Bill Clinton here. What do you mean by "cause"? Because if you use it in a broad, a very broad sense, anything can cause chronic pain, in a very broad sense.
>
> Q. I'm going to ask the question in a yes-or-no form, and then I'm going to ask if you can answer it yes or no. Yes or no: Can TVT mesh cause chronic pain in women?
>
> THE WITNESS: I cannot answer that specific question.
>
> Q. Okay. Yes or no: Can TVT mesh cause chronic dyspareunia?
>
> THE WITNESS: Again, I cannot answer that specific question.

(Carbone TVT Day 1, Ex. D, at 132:15-18, 103:9 to 104:5).

As such, he should be precluded from giving any opinions related to design of the subject products.

CONCLUSION

Based on the foregoing, Dr. Carbone should be precluded from giving opinions on (1) the safety and efficacy of Defendants' products based on his own clinical practice; (2) the adequacy of Defendants' product warnings and instructions for use ("IFU"), or (3) the design of Defendants' transvaginal mesh products at issue, including the safety and efficacy of those devices.

Dated: April 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on April 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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